

REMARKS

Indefiniteness Rejection

Claim 1-8¹ were rejected under 35 USC §112, second paragraph, as being indefinite. (Paper No. 22 at 2). In making the rejection, the Examiner contended that:

The term "comprises" cited in claim 1 is inclusive and fails to exclude unrecited steps. The use of the term comprising to introduce claimed structure means that the ingredients covered by these claims may involve more elements than those positively recited. *Ex parte Gottzein et al.*, 168 USPQ 176 (PTO Bd. App. 1969). Comprising leaves the claim open for inclusion of unspecified ingredients even in major amounts. *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948) (*Id.*).

For the reasons set forth below, the rejection is traversed.

As is well settled, all that is required to comply with 35 USC §112, second paragraph, is that the metes and bounds of what is claimed be determinable with a reasonable degree of precision and particularity. *Ex parte Wu*, 10 USPQ2d 2031, 2033 (BPAI 1989). There is nothing vague or indefinite about the recited process. One skilled in the art would readily recognize what is being claimed and the Examiner has not even contended otherwise, much less articulated any facts to support the rejection. For this reason alone, the rejection should be withdrawn.

Moreover, the use of the transitional term "comprising" is commonplace in patent law. As explained in MPEP § 2111.03 (8th Ed. August 2001, p. 2100-49):

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("**Comprising**" is a term of art

¹ We note that claims 7 and 8 were cancelled in the RESPONSE TO OFFICE ACTION UNDER RULE 116 INCLUDING AMENDMENT, dated December 5, 2001. The Amendment was entered by the Examiner in the instant Office Action. (See Paper No. 22 at 2.) Therefore every rejection of those claims is moot.

used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("***comprising***" ***leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"***). (*Id.*) (Emphasis added.)

indeed, the legitimacy of the use of the term "comprising" in patent claims it is hardly surprising, and the phrase "process comprises" is found in the claims of over 321,000 patents since 1976 alone. (See Exhibit 1, showing only the first 50 of the reported results.)

Moreover, with all due respect, it is astonishing that after nearly three years of prosecution the Examiner has suddenly deemed the transitional phrase "comprising" to be indefinite. The Examiner's statement of the rejection demonstrates that she clearly understands the transitional phrase "comprising" and the breadth of the claims, i.e. that the term comprising in claim 1 is inclusive. That, however, does not render a claim indefinite. As the MPEP also makes clear, "BREADTH IS NOT INDEFINITENESS" (See Title of MPEP § 2173.04 (8th Ed. August 2001, p. 2100-195).

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. (MPEP § 2173.04)

However, breadth is all that the rejection alleges. This is not, and in fact has been explicitly rejected as, enough to support a *prima facie* case for indefiniteness. For this additional reason, the rejection is erroneous as a matter of fact and law, and must be withdrawn.

Should the rejection be maintained, the Examiner is requested to provide authority for the proposition that the use of the transitional phrase "comprising" renders a claim *prima facie* indefinite.

Enablement Rejection

Claims 1-3, 5, and 8 were rejected under 35 USC §112, first paragraph, on the asserted grounds that the specification "does not reasonably provide support enablement for 'with back-pressure regulation'." (Paper No. 22 at 3.)

For the reasons set forth below, the rejection is traversed.

In making the rejection, the Examiner merely made the completely unsupported assertion that the "specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." (*Id.*) The Examiner requires "Applicant must show the support for the amended claim." (*Id.*)

As is well settled, it is the Examiner's burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). To carry this burden, the Examiner must identify and clearly articulate the factual bases and supporting evidence that allegedly establish that **undue experimentation** would be required to carry out the claimed invention. *Id.* at 370. "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue." MPEP § 2164.01 (8th Ed. August 2001, p. 2100-175) citing *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).

Many factors must be considered in determining whether there is sufficient evidence to support a rejection for lack of enablement and whether the necessary experimentation is undue. "These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure." MPEP §2164.01(a) (8th Ed. August 2001, p. 2100-175) citing *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

It is well settled, that the "determination that 'undue experimentation' would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is **a conclusion reached by weighing all the above noted factual considerations.**" (*Id.*)

Initially, we note that the rejection fails to assert that any experimentation is required to make and use the claimed invention, much less, undue experimentation. Further, no individual claim is even discussed. Accordingly, the rejection is devoid of the required analysis of what, if any experimentation, is needed to make and use the invention as claimed. For this reason alone, the rejection is deficient and must be withdrawn.

Moreover, the rejection fails to make the requisite factual inquiry to support a conclusion that *undue* experimentation is required to make and/or use the claimed invention. In fact, the rejection is bereft of any factual inquiry whatsoever. To the contrary, the Examiner has simply posited in conclusory fashion that the "specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." (Paper No. 22 at 3.) An unsupported conclusion is not, indeed cannot be, a proper *prima facie* case for lack of enablement. Absent the required factual analysis, the rejection is infirm as a matter of fact and law. For this additional reason the rejection must be withdrawn.

Although believed unnecessary, we discuss below evidence of record, not considered by the Examiner, that further supports the withdrawal of the enablement rejection. As noted in our RESPONSE TO OFFICE ACTION UNDER RULE 116 INCLUDING AMENDMENT, dated December 5, 2001, "[s]upport for these amendments is found in the specification at, for example, page 5, lines 1-9, in the Example, in figure 2, and in original claim 2." (Page 3-4.) As the specification makes clear, "to keep the carbon dioxide used in the mobile phase in the process in accordance with the invention in the supercritical or liquid range, certain temperature and pressure conditions must be maintained...." (Page 5, lines 1-3.) More specifically, the specification recites that the "process is conveniently carried out ... at a pressure of about 7.5 MPa to about 32.0 MPa. Preferably, ... the respective pressure range is 7.5 to 15 MPa." (*Id.* at lines 5-9.) In addition the Example recites that, "the mobile phase can be operated in the supercritical range (above about 31°C and 7.3 MPa in the case of pure CO₂)..." (Page

6, lines 2-3.) To maintain the pressure required to keep the carbon dioxide in the supercritical range a back-pressure regulator is required. In fact, the required back-pressure regulator is shown in Figure 2 (flow diagram of the apparatus of the Example) as the valve between the chromatography column and the fractionation/separation unit.

In addition, to demonstrate that one of skill in the pertinent art would be required to carry out undue experimentation, the Examiner must consider the knowledge in the art at the time of filing of the application. "In fact, **a patent need not teach, and preferably omits, what is well known in the art.**" MPEP § 2164.04 (8th Ed., August 2001, p. 2100-174). The need for back pressure and a back-pressure regulator is well known in the art. In fact, Higashidate *et al.* (Journal of Chromatography, 515, pp. 295-303 (1990)) ("Higashidate"), cited by the Examiner in making the 35 USC § 103 rejection, specifically discloses both. "SFC was performed by programmed extraction-elution method. The pressure of the back-pressure regulator was changed stepwise to 8, 12 and 20 MPa...." (Page 297.)

Accordingly, the Specification "contain[s] sufficient information regarding the subject matter of the claims as to enable on skilled in the pertinent art to make and use the claimed invention." See MPEP 2164.04 (8th Ed. August 2001, p. 2100-174). For this additional reason, the rejection is factually deficient and should be withdrawn.

Should the rejection be maintained, the Examiner is requested to provide authority for the proposition that an unsupported conclusion that "the specification does not enable one of skill in the art ... to make and use the invention..." is sufficient to support a rejection for lack of enablement.

Obviousness Rejection

Claims 1-8 were rejected solely under 35 USC § 103(a) as being unpatentable over Higashidate and Nakamura *et al.* (DN 120:220844, CAPLUS, abstract of JP 05345898) ("Nakamura"). (Paper No. 22 at 4).

For the reasons set forth below the rejection, respectfully is traversed.

Higashidate discloses a method of isolating eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). (Page 302.) Higashidate discloses extraction of "methyl esters EPA and DHA in esterified fish oil" by "supercritical fluid extraction with carbon dioxide and direct[] introduc[tion] into a silica gel column coated with silver nitrate." Followed by, fractionation "by reducing the pressure of column effluent to atmospheric." (Abstract.) Higashidate discloses that this method results in enrichment of the concentration of EPA and DHA methyl esters "from 12% to 93% and from 12% to 82%, respectively." (Abstract; see also page 298.)

Nakamura is an abstract of a Japanese patent. Nakamura is reproduced below:

The process using no aliph. hydrocarbons comprises dissolving raw material oil in liquefied CO₂ and passing the liq. under supercrit. conditions through a packed column. Placing 10 g crude Macadamia nut oil (APHA color 100) in a column packed with 10 g silica gel and passing liquefied CO₂ through the column at 50 atm gave a liq., which after CO₂ evapn. yielded 8.9 g oil with APHA color 5 and no malodor.

In making the rejection, the Examiner asserted that the cited documents disclose "separation and isolation of components on silica gel as the stationary phase and super critical carbon dioxide as mobile phase...." (Paper No. 22 at 4.) The Examiner further asserted, Higashidate discloses "enrichment of eicosapentaenoic (EPA) and docosahexaenoic acid (DHA) | from 12% to 93% and from 13% to 82%

respectively. Methyl esters of EPA and DHA in esterified fish oil were extracted by supercritical fluid extraction with carbon dioxide....” (*Id.*) The Examiner acknowledged, however, that the “[i]nstant claims differ from the reference in claiming isolation of specific compounds vitamin D3 and previtamin D3 from the mixture whereas” the documents cited disclose “methods for separation of various compounds by supercritical carbon dioxide....” (*Id.* at 5.)

To fill the acknowledged gap, the Examiner offers nothing more than unsupported suppositions. “This **technique is now commonly used.**” “Size of the silica gel and pressure are selected depending on the type of compounds intended to isolate.” “**One skilled in the art who is familiar with the separation techniques would know to use** the size of the particles and **other adjustments** in order to enhance the yield of the process.” “[T]here is nothing unobvious is seen to separate vitamin D3 and previtamin D3 from the mixture by using supercritical carbon dioxide and silica gel for the isolation of the said compounds.” (*Id.*)

The Examiner asserted “[i]t **would have been obvious** to one skilled in the art **to be motivated** to separate components of the mixture by using supercritical carbon dioxide as the mobile phase and silica gel as stationary phase.” (*Id.*) And, then concluded that “the Examiner’s ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).” (*Id.* at 6.)

Initially, we note that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ

785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152. Furthermore, as is fundamental, all properties and attributes of a claimed invention must be considered by the Examiner. *In re Antonie*, 195 USPQ 6, 8 (CCPA 1977).

The rejection uses the wrong standard for determining obviousness. The rejection relies upon an “[i]t would have been obvious ... to be motivated ...” standard that is not found in the statute or precedential authority. As is well settled, an Examiner cannot establish obviousness by locating a reference which describes some aspects of a patent applicant's invention without also providing evidence of the motivating force which would *impel* one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). The rejection fails to provide any reason why one would be motivated, let alone impelled, to modify Higashidate or Nakamura in the manner suggested by the Examiner. Whatever the “Examiner’s ultimate legal conclusion is,” a finding that “[i]t would have been obvious ... to be motivated...” is not enough to support a *prima facie* rejection under 35 U.S.C. § 103. Thus, the rejection fails to set forth the facts and reasoning required to support a *prima facie* case of obviousness. For this reason alone, the rejection should be withdrawn.

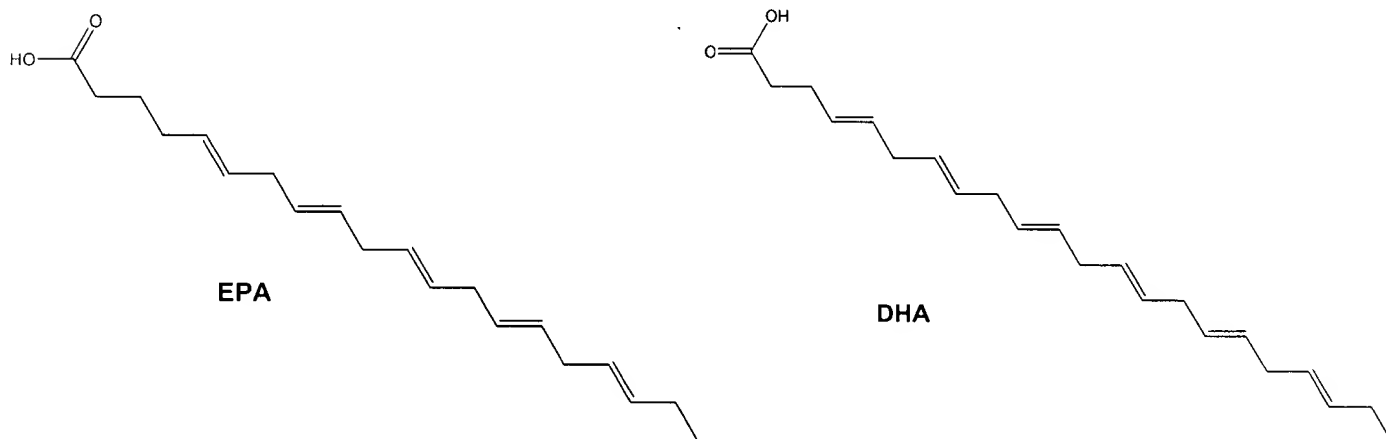
Further, an Examiner’s belief or conjecture is no substitute for statutory prior art. *In re Kratz*, 201 USPQ 71, 76 (CCPA 1979) *citing*, *In re Antonie*, 195 USPQ 6 (CCPA 1977). (“We have previously rejected the argument that undirected skill of one in the pertinent art is an adequate substitute for statutory prior art.”).

The Examiner asserted that the "***technique is now commonly used.***" "Size of the silica gel and pressure are selected depending on the type of compounds intended to isolate;" and "[o]***ne skilled in the art who is familiar with the separation techniques would know to use*** the size of the particles and ***other adjustments***" (Paper No. 22 at 5.) The rejection, however, fails to provide statutory prior art (or any other evidence) to support any of these assertions.

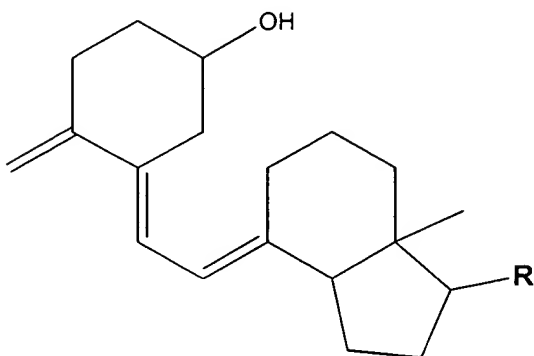
Because the rejection has substituted conjecture of what one skilled in the art would believe for the required statutory reference, *i.e.*, a prior art disclosure that vitamin D₃ and previtamin D₃ may be separated by SFC methods (*In re Kratz*, 201 USPQ at 76), and because the rejection is not supported by the kind of specificity required to sustain a conclusion of obviousness (*Ex parte Humphreys*, 24 USPQ 2d 1255, 1262 (BPAI 1992) ("The Examiner's rejection is not specific as to how one of ordinary skill in the art would have found it (the claimed invention) obvious")) the rejection should be withdrawn.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, "to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 citing *In re Royka*, 180 USPQ 580 (CCPA 1974).

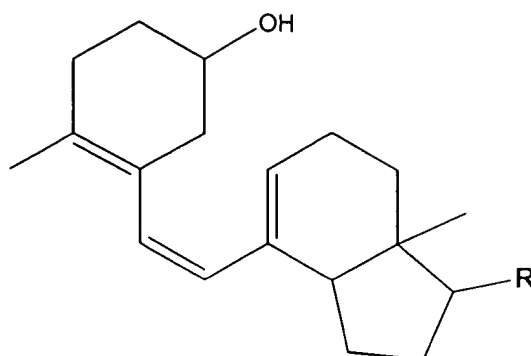
The rejection, however, fails to account for each and every element of the claimed invention. The claimed invention recites separating “vitamin D₃ or previtamin D₃” from a mixture. Neither Higashidate, nor Nakamura disclose or suggest the separation of vitamin D₃ or previtamin D₃ in any manner, much less the separation of vitamin D₃ or previtamin D₃ by a SFC method. Higashidate discloses a method for enriching the concentration of two polyunsaturated fatty acids (PUFAs), EPA and DHA. These PUFAs are found in esterified fish oils, and Higashidate discloses a method for enriching EPA and DHA from such oil. PUFAs are fatty acids with multiple carbon-carbon double bonds.



However, vitamin D₃ and previtamin D₃ are not PUFAs and exhibit absolutely no structural similarity to PUFAs.



Vitamin D₃



Previtamin D₃

In addition, Higashidate specifically notes the limitations of the method disclosed.

The extraction vessel was used in order to introduce only constituents of the fish oil that are soluble in supercritical carbon dioxide into the separation column. This was successful in the fractionation of EPA and DHA methyl esters. However, direct injection of the esterified fish oil was unsuccessful in this fractionation, because constituents of the esterified fish oil insoluble in supercritical carbon dioxide precipitated and covered the stationary phase, resulting in the decrease selectivity of the column. (Page 297.)

Accordingly, the disclosure of Higashidate can only be extended as far as separating EPA and DHA from a fraction of esterified fish oil that is soluble in supercritical carbon dioxide. Accordingly, nothing in Higashidate discloses or suggests separating vitamin D₃ or previtamin D₃ from a mixture containing vitamin D₃ or previtamin D₃.

Nakamura discloses "placing 10 g crude Macadamia nut oil (APHA color 100) in a column packed with 10 g silica gel and passing liquefied CO₂ through the column at 50 atm. gave a liq[uid], which after CO₂ evap[oration] yielded 8.9 g oil with APHA color 5 and no malodor." We note that there is nothing in Nakamura even

remotely related to vitamin D₃ or previtamin D₃. In addition, it is not clear what if anything was separated by this process. All that is disclosed is that the process used 10 g of Macadamia nut oil to produce 8.9 g of some ending oil, and that the APHA color went from 100 to 5. Nakamura does not disclose what the ending oil is, or what the APHA color change indicates. And, the rejection offers nothing to fill these gaps. The Examiner apparently recognized the infirmity of this document as cited against the claimed invention, and only asserted that "Nakamura teaches use of silica gel column chromatography in supercritical carbon dioxide separation technique." (Paper No. 22 at 4.) This is the only discussion of Nakamura, and even this overstates what Nakamura actually discloses. Nakamura does not mention separation in any manner. At best Nakamura discloses use of silica gel column chromatography and supercritical carbon dioxide on Macadamia nut oil. That, however, is not what is claimed, and nothing in the rejection points to any evidence that Nakamura discloses or suggests the process as claimed.

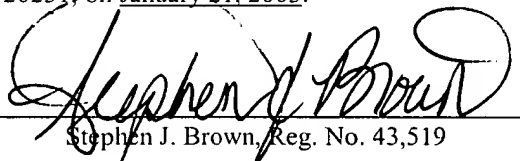
Although the rejection states that the claims are rejected over Higashidate **"and"** Nakamura, the rejection does not even attempt to combine the documents, and therefore, offers no motivation to do so. (Paper No. 22 at 4.) Accordingly, the rejection is again deficient. Moreover, even in combination the documents do not disclose or suggest the claimed invention. In combination, the documents disclose, at best, enrichment of EPA or DHA from Macadamia nut oil (if, possible), or a process for lowering the APHA color level of esterified fish oil. Neither of these is the claimed invention.

Accordingly, the rejection is factually deficient in four distinct ways: 1) The rejection points to no motivation or suggestion to combine Higashidate and Nakamura; 2) Even in combination Higashidate and Nakamura do not disclose or suggest the claimed invention; 3) Higashidate discloses enrichment of PUFAs which is nothing like the vitamin D₃ or previtamin D₃ separation claimed; and 4) Nakamura discloses neither vitamin D₃ or previtamin D₃, nor the separation of any compound. For these additional reasons, the rejection is factually deficient and should be withdrawn.

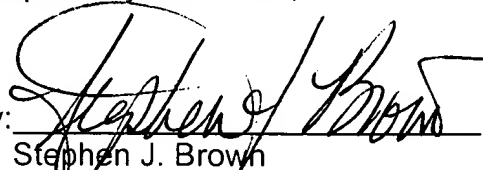
In summary, the rejection is both legally and factually insufficient to support a *prima facie* rejection under 35 U.S.C. § 103. Accordingly, the rejection should be withdrawn.

Accordingly, for the reasons set forth above withdrawal of the rejections and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Non-Fee Amendment, Commissioner for Patents, Washington, D.C. 20231, on January 21, 2003.


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